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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Farid Vaghefi

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EXAMINER

ROYDS, LESLIE A

ART UNIT

PAPER NUMBER

1614

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,727	<b>Applicant(s)</b> VAGHEFI ET AL.	
	<b>Examiner</b> LESLIE A. ROYDS	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7,9 and 11-26 is/are pending in the application.
- 4a) Of the above claim(s) 12-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-5,7,9,11 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

**Claims 1, 4-5, 7, 9 and 11-26 are presented for examination.**

Applicant's Amendment filed October 31, 2008 has been received and entered into the present application.

Claims 1, 4-5, 7, 9 and 11-26 are pending. Claims 12-23 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 25-26 are newly added. Claims 1, 4 and 9 are amended. Claims 1, 4-5, 7, 9, 11 and 24-26 are under examination.

Applicant's arguments, filed October 31, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter***

##### ***(New Grounds of Rejection)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, 7, 9, 11 and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, the specification and claims as originally filed fail to provide adequate written description for the newly added limitations directed to (1) crushing, compressing, fracturing, tumbling, rolling or milling said matrix *before coming in contact with water* (claims 1 and 9); (2) does not

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substantially modify the dissolution rate of *said active water soluble compound* thereafter (claims 1 and 9); (3) wherein a *pressure-pulse is applied to a flowable mixture of said coating material and said active water soluble compound to form a pressure-treated matrix* (claim 25); and (4) *wherein said pressure-treated matrix is spray cooled to form microspheres* (claim 26).

MPEP §2163 states, “The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))...Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).”

Regarding (1) and (2), relevant disclosure was found at p.6-7 of the instant specification, which states: “The application of mechanical stress to the preferred abuse-resistant composition of the present invention results in an insubstantial increase in the immediate aqueous dissolution of active in said composition. More particularly, such application of stress increases the aqueous dissolution of active in

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the present compositions by less than about fifteen percent, and more preferably less than about ten percent, of the total pharmaceutically effective dosage amount in the first hour of in vitro dissolution testing. Furthermore, the dissolution rates of the preferred compositions are not substantially modified after the first hour of testing. The mechanical stress applied to the compositions may be of any sort, and includes crushing, compressing, fracturing, tumbling, rolling, milling and the like. A mechanical stress most likely to be used for abuse of said compositions is crushing."

However, the disclosure of the application of mechanical stress, such as crushing, compressing, fracturing, tumbling, rolling or milling of the matrix (i.e., that comprising the coating material and within which the particles are distributed) without specifying the time at which the mechanical stress must be applied fails to provide adequate written support to now narrow the claims to read upon the application of mechanical stress (i.e., crushing, compressing, fracturing, tumbling, rolling or milling) specifically before coming in contact with water. This is a concept that is not adequately supported by the written description of the invention as provided in the specification and claims as originally filed because the generic disclosure of applying mechanical stress at *any* time does not provide adequate support to then narrow the claims to read upon applying mechanical stress specifically *before coming in contact with water*. This newly amended limitation represents a narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure and clearly circumscribes a concept that was not in Applicant's possession at the time of the invention.

Furthermore, the disclosure of the dissolution rate of the preferred compositions not being substantially modified after the first hour of testing fails to provide adequate written support to now narrow the claims to read upon the dissolution rate of the *active water soluble compound* (i.e., the active water soluble compound capable of abuse, which is contained within the composition as discrete particles distributed throughout the matrix) not being substantially modified after the first hour of testing. This is a

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concept that is not adequately supported by the written description of the invention as provided in the specification and claims as originally filed because the disclosure of not substantially modifying the dissolution rate of the disclosed composition (which contains the active water soluble compound as discrete particles wetted with a coating material and distributed throughout a matrix comprising the coating material) after the first hour of testing does not provide adequate support to then narrow the claims to read upon the same effect (i.e., not substantially modifying the dissolution rate after the first hour of testing) on the active water soluble compound *alone*. This newly amended limitation represents a narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure and clearly circumscribes a concept that was not in Applicant's possession at the time of the invention.

Regarding (3) and (4), relevant disclosure was found at p.19-20 of the instant specification, which states: "The present invention also relates to the process for the manufacture of the present microspheres. The present sustained release pharmaceutical compositions having a reduced potential for abuse may be prepared by applying a pressure force to a mixture comprising particles of a compound having a potential for abuse and a water insoluble material thereby resulting in surface coated particles and incorporating the resulting surface coated particles into a pharmaceutical composition that when subjected to stress does not increase substantially the immediate release of said compound in an aqueous environment. A particularly preferred method is wherein the aforesaid pressure force is applied to a dispersion of said particles in a flowable water insoluble medium." Additionally relevant disclosure was found at p.20-21 of the instant specification, which states: "A special embodiment of the present invention forms microspheres from the surface-coated particles by the process of spraying, into a chilling zone maintained at a temperature below the solidification temperature of the water insoluble fluid matrix material, a flowable dispersion of active particles in the water insoluble fluid matrix. A most preferred process employs conditions that impart an electrostatic charge to said water insoluble matrix and that form droplets of said dispersion. The process

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preferably maintains the fluidity of, and charge on, the droplets for a time sufficient to distribute the particles electrostatically within the droplets, prior to the solidification of the droplets into microspheres."

However, the disclosure of the application of a pressure-force (defined later at p.20 of the instant specification as encompassing the use of a pressure-pulse as now claimed in new claim 25) to a dispersion of said particles (i.e., the particles of the compound having a potential for abuse and the water-insoluble material) in a flowable water insoluble medium fails to provide adequate written support to now broaden the claims to read upon the application of a pressure-pulse (i.e., a type of pressure force defined at p.20 of the instant specification) to a "flowable mixture of said coating material and said active water soluble compound" as now claimed. This is a concept that is not adequately supported by the written description of the invention as provided in the specification and claims as originally filed because the disclosure of, specifically, a dispersion of particles comprising the compound and the water-insoluble coating material in a flowable water insoluble medium does not provide adequate support to then broaden the claims to read upon the use of a "flowable mixture" of the same. This newly added limitation represents a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure and clearly circumscribes a concept that was not in Applicant's possession at the time of the invention.

Furthermore, the disclosure of applying a pressure force to a mixture comprising particles of a compound having a potential for abuse and a water insoluble material thereby resulting in surface coated particles fails to provide adequate written support to now broaden the claims to read upon the formation of a pressure-treated matrix as now claimed. This is a concept that is not adequately supported by the written description of the invention as provided in the specification and claims as originally filed because the disclosure of, specifically, the application of a pressure force to the mixture to form surface-coated particles does not provide adequate support to then claim the same manner of applying a pressure force to the mixture to form a pressure-treated matrix, particularly in view of the fact that the matrix as now

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claimed in instant claims 25 and 26 does not specifically require any surface coating of the particles that are present. This newly added limitation represents a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure and clearly circumscribes a concept that was not in Applicant's possession at the time of the invention.

Lastly, the disclosure of the formation of microspheres from the surface-coated particles via the process of spraying, into a chilling zone maintained at a temperature below the solidification of the water insoluble fluid matrix material, a flowable dispersion of active particles in the water insoluble fluid matrix fails to provide adequate written support to now broaden the claims to read upon the formation of microspheres by spray cooling a pressure-treated matrix of the coating material and the active water soluble compound under *any* conditions. This is a concept that is not adequately supported by the written description of the invention as provided in the specification and claims as originally filed because the disclosure of forming microspheres from *surface-coated particles* by *spraying a flowable dispersion of active particles in the water insoluble fluid matrix into a chilling zone maintained at a temperature below the solidification temperature of the water insoluble fluid matrix material* does not provide adequate support to then broaden the claims to read upon the formation of microspheres from a pressure-treated matrix comprising the coating material and active water soluble compound via spray cooling under *any* conditions. This newly added limitation represents a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure and clearly circumscribes a concept that was not in Applicant's possession at the time of the invention.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed



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to provide the necessary teachings, by describing the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concepts of (1) crushing, compressing, fracturing, tumbling, rolling or milling said matrix *before coming in contact with water* (claims 1 and 9); (2) does not substantially modify the dissolution rate of *said active water soluble compound* thereafter (claims 1 and 9); (3) wherein a *pressure-pulse is applied to a flowable mixture of said coating material and said active water soluble compound to form a pressure-treated matrix* (claim 25); and (4) *wherein said pressure-treated matrix is spray cooled to form microspheres* (claim 26).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 7, 9, 11 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Palermo et al. (U.S. Patent No. 6,228,863; 2001), already of record, for the reasons of record set forth at p.2-4 of the previous Office Action dated August 26, 2008, of which said reasons are herein incorporated by reference.

Newly amended claim 1 now recites that the active compound capable of abuse is “water-soluble”. The claim remains properly included in the instant rejection because instant claim 7 defines the compounds capable of abuse as narcotics, which are further defined in instant claim 24 as, *inter alia*, oxycodone, hydroxycodone, codeine, etc. Though Palermo et al. is silent as to the specific property of the disclosed narcotic agents (*inter alia*, oxycodone) as being water-soluble, the use of the same compound(s)

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as instantly claimed (and described as being water-soluble) is considered to necessarily have the claimed water solubility, whether recognized by the patentee or not. Products of identical chemical composition cannot exert mutually exclusive properties. Please reference MPEP §2112. Please also see *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. and Inter. 1993), which stated, “The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. Patent to Dart disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.” Analogously, in the present case, though Palermo et al. do not explicitly note the water solubility of the disclosed narcotic agents (including oxycodone, which appears in instant claim 24 as one of the “water-soluble” compounds usable in the instant composition), such a property, though only now recognized by Applicant, is a property of the compound(s) of Palermo et al. that is necessarily present, absent factual evidence to the contrary.

Furthermore, instant claim 1 has now been amended to require that: (1) the discrete particles of the active water soluble compound capable of abuse are distributed throughout a matrix comprising the water-insoluble coating material and (2) wherein crushing, compressing, fracturing, tumbling, rolling or milling said matrix before coming in contact with water increases the aqueous dissolution of said active water soluble compound in said composition by less than about 15% of said pharmaceutically effective amount in the first hour, and does not substantially modify the dissolution rate of said active water soluble compound thereafter. Such limitations are met by Palermo et al. because:

(1) Palermo et al. teaches a controlled release formulation of an opioid analgesic, such as, *inter alia*, oxycodone, wherein the formulation can be a multiparticulate formulation that includes a sustained release carrier, which is incorporated into a matrix and applied as a sustained release coating that may

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further contain plasticizers that are water-insoluble. Please see Palermo et al. at the abstract, col.3, 1.38-col.5, 1.10; col.14, 1.33-68 and col.17, 1.24-41. Thus, the application of a matrix formed from the sustained release coating containing water-insoluble plasticizers to a particulate formulation of the opioid analgesic to wet the surfaces of the particles thereof is evidence that the particles of the opioid analgesic would be distributed throughout the matrix comprising the coating material via the act of immersing the particles of the opioid compound in the coating.

(2) The limitations directed to the ability of the composition to increase the aqueous dissolution of the active water soluble compound when subjected to crushing, etc. are characterizations of the function and/or effect of the composition when subjected to such mechanical actions. Though Palermo et al. is silent as to such functions of the disclosed composition, it is noted that the teaching of a composition with identical formulation components and characteristics (i.e., same active agents, same matrix, same coating materials, same structural relationships between the components, etc.) must necessarily possess the same functional properties of increasing the aqueous dissolution of the active water soluble compound when subjected to crushing etc., even though such properties may not have been appreciated by the patentee(s) at the time of the invention. This is because products of identical chemical composition cannot have mutually exclusive properties because a chemical composition and its properties are inseparable. Thus, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims must be necessarily present, absent factual evidence to the contrary. Please see MPEP §2112. Equivalent rationale is applied to newly amended claim 9, which limits the subject matter to the act of “crushing said matrix”.

*In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe includes functions and/or properties that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not

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possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the newly cited function and/or property at the time of invention, so long as the function and/or property can be demonstrated to be reasonably expected to be present. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

Newly added claims 25-26 are properly included in the instant rejection because each defines steps of making the instantly claimed abuse-resistant composition of instant claim 1, i.e., product-by-process claims, wherein a pressure-pulse is applied to a flowable mixture of said coating material and said active water soluble compound to form a pressure-treated matrix (claim 25), wherein said pressure-treated matrix is spray cooled to form microspheres (claim 26). Though it is noted that Palermo et al. does not explicitly teach these steps of instant claims 25-26 to prepare the composition of instant claim 1, Applicant is reminded that these limitations are process limitations (i.e., directed to a process of obtaining the final abuse-resistant composition) and, thus, fails to materially or structurally limit the claimed composition or components thereof as a whole since the prior art already teaches the instantly claimed product. Accordingly, since the cited reference(s) clearly anticipates the same composition for the reasons *supra* and those already of record, the process Applicant intends to prepare the claimed composition is immaterial to the composition as a whole. As directed by the MPEP at §2113, "Even though product-by-process claims are limited by and defined by the process, *determination of patentability is based on the product itself*. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process"

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(see *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985 and MPEP §2113)). Moreover, MPEP §2113 states, “Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, *the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.*” (emphasis added)

*Response to Applicant’s Arguments*

Applicant traverses the instant rejection, stating that Palermo et al. fails to disclose or suggest a means for retarding the aqueous dissolution of the active agent if the composition is abused. Applicant asserts that the instant invention frustrates the abuser by setting up a formulation barrier that inhibits aqueous dissolution and prevents the abuser from achieving a "high" via crushing the composition for nasal inhalation. Applicant alleges that the instant invention is ineffective for achieving a high via crushing and nasal inhalation since the active agent is effectively prevented from being rapidly released via these methods.

Applicant’s traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant alleges that Palermo et al. fails to disclose or suggest a means for retarding the aqueous dissolution of the active agent if the composition is abused. This is unpersuasive. Neither the claims nor Applicant has specifically pointed to the element (or “means”) of the instantly claimed composition that is responsible for retarding the aqueous dissolution of the active agent if the composition is abused and how this element is not found in Palermo et al. Moreover, in view of the fact that the composition of Palermo et al. meets each and every physical and structural requirement of the instant claims, the functional properties thereof (as described by Applicant’s claims) must necessarily be present in the composition of Palermo et al., absent factual evidence to the contrary, because products of identical composition cannot have mutually exclusive properties. See MPEP §2112. Thus, whatever properties

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Applicant may have newly recognized from this same combination and arrangement of elements as taught in the prior art by Palermo et al. is a function of the composition and must also be present in the invention of Palermo et al. if subjected to the same conditions, absent evidence to the contrary.

Moreover, note that the invention of Palermo et al. is clearly functional at least to reduce the abuse potential of the opioid analgesic contained therein, though the reference may not explicitly describe how the disclosed composition functions to do so. Thus, a discovery or explanation as to how this is achieved, such as, e.g., in instant claim 1, fails to patentably distinguish the instant claims over that of the prior art to Palermo et al. because the discovery of unappreciated properties that appear to be necessarily present in the invention of Palermo et al. does not amount to a patentably new composition unless Applicant demonstrates that such characteristics are, in fact, *not* present in the prior art product.

Secondly, and lastly, Applicant's traversal fails to raise issues of material fact with regard to what Palermo et al. teaches and why these teachings do not directly anticipate the instantly claimed invention. Though Applicant asserts particular advantages of the instant invention, i.e., that it frustrates the abuser by setting up a formulation barrier that inhibits aqueous dissolution and prevents the abuser from achieving a "high" via crushing the composition for nasal inhalation, and also that it is ineffective for achieving a high via crushing and nasal inhalation since the active agent is effectively prevented from being rapidly released via these methods, Applicant is reminded that Palermo et al. explicitly teaches a composition for the same purpose of reducing abuse of opioid analgesic compounds, wherein the composition comprises the same physical elements in the same structural arrangement as that instantly claimed. Please see the reasons described *supra* and those made of record at p.2-4 of the Office Action dated August 26, 2008. For these reasons, the teachings of Palermo et al. clearly anticipate the instant claims (and further in view of the fact that Applicant has failed to show otherwise).

Consequently, Applicant's arguments fail to clearly point out the patentable novelty which he thinks the claims present in view of the state of the art disclosed by the reference cited. In addition, the

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arguments also fail to specifically point out disagreements with the Examiner's contentions and/or how the claims avoid the reference or are distinguished from the same and are, therefore, clearly not persuasive in establishing that the evidence of novelty outweighs that proffered to support the instant conclusion of a lack of novelty.

For these reasons *supra*, and those previously made of record at p.2-4 of the Office Action dated August 26, 2008, rejection of claims 1, 4-5, 7, 9, 11 and 24-26 is proper.

### ***Conclusion***

Rejection of claims 1, 4-5, 7, 9, 11 and 24-26 is proper.

Claims 12-23 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE A. ROYDS whose telephone number is (571)272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/  
Patent Examiner, Art Unit 1614

April 6, 2009

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614